

**REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated November 29, 2001 are respectfully requested. Applicants petition the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

Applicants thank the Examiner for an indication that claims 59-62, 67-68, 70-73, and 92-100 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim.

**I. Amendments****A. Specification**

The specification has been amended to correct obvious typographical errors and for correct grammar.

**B. Claims**

Claims 10, 12-17, 20-22, 26-28, 30, 38, 45, 46, 49-52, 54-56, 63-66, 76, 78-81, 85-88, 90, and 91 stand canceled.

Claim 1 is amended for clarity. Claim 1 is further amended to recite each of the resilient member having a tissue piercing distal end. Support for this amendment can be found in original claim 1. Claim 1 is additionally amended to recite at least some of the resilient members being electrodes which can be coupled to an RF energy source for ablating tissue. Support for this amendment can be found in original claims 75 and 76. Claim 1 is additionally amended to clarify that the tissue type is distinguished using the sensor array to measure a spectral profile. Support for this amendment can be found page 7, line 28 through page 8, line 1.

Claim 2 is amended to clarify that the monitoring is done using the spectral profile.  
Support for this amendment can be found on page 7, line 28 through page 8, line 5.

Claims 3, 7, 9, 11, 29, 39, 40, 59, 69, 83, and 89 are amended for clarity.

Claims 4, 37, 58, 75, 76, 84, and 92 are amended for proper markush format.

Claims 6 and 32 are amended for consistent terminology with claim 1.

Claim 31 is amended to depend from claim 1.

Claim 57 is rewritten in independent format.

Claim 74 is amended to clarify that the marking agent is used to detect a boundary or volume of a tissue. Support for this amendment can be found in original claim 57, and on page 3, lines 9-13 and 25-29.

Claim 97 is amended to correct an obvious typographical error.

By these amendments, no new subject matter has been added.

new issues (spectral)

## II. Rejection under 35 U.S.C. §112, second paragraph

Claim 13 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 13 stands canceled. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

## III Rejection under 35 C.F.R. §102

Claims 1-39, 42-46, 57-58, 63, 65, 69, 74-77, 78-91, and 101-104 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gough *et al.* (U.S. Patent No. 5,735,847). These rejections are respectfully traversed.

### A. The Present Invention

The present invention describes a method of treating a tumor comprising providing a tissue biopsy and treatment apparatus for detecting and treating a tumor, where the apparatus comprises an elongated delivery device including a lumen and a sensor array deployable from the elongated delivery device. The sensor array includes a plurality of resilient members each having a tissue piercing distal portion. At least one of the plurality of resilient members is positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state. At least one of the plurality of resilient members includes a sensor and the sensor array has a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site. At least some of the plurality of resilient members are electrodes which can be coupled to an RF

energy source for ablating tissue when electrical energy is supplied to the electrodes from the source. The apparatus is positioned at a target tissue site. A tissue type is distinguished utilizing the sensor array to measure a spectral profile of at least one portion of the tissue site. The electrodes are deployed to define an ablation volume that includes at least a portion of the tumor volume. Energy is delivered to the electrodes to ablate or necrose at least a portion of the tumor volume. An amount of tumor volume ablation is determined utilizing the sensor array.

#### B. The Prior Art

GOUGH ET AL. describe a multiple antenna ablation device. The multiple antenna device includes a primary antenna with a lumen and a longitudinal axis and a distal end sufficiently sharp to pierce tissue, and a secondary antenna at least partially positioned in the secondary antenna. The secondary antenna includes a distal portion configured to be deployed from the lumen in a lateral direction relative to the longitudinal axis, wherein at least a part of a deployed secondary antenna distal portion has at least one radius of curvature. The device is configured to be coupled to an energy source. The device further includes a cooling element coupled to the primary antenna.

#### C. Analysis

Gough *et al.* fail to teach distinguishing a tissue type utilizing the sensor array to measure a spectral profile of at least one portion of the tissue site. Nowhere do Gough *et al.* make any mention of measuring a spectral profile.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

#### VI. Rejections under 35 C.F.R. §103

Claims 47-56 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Hoey *et al.* (U.S. Patent No. 6,409,722).

Claims 40 and 41 were rejected under 35 U.S.C. §103 as allegedly obvious over Gough *et al.* in view of Edwards *et al.* (U.S. Patent No. 6,092,528).

A. The Present Invention

The present invention is described above.

B. The Prior Art

GOUGH ET AL. is described above.

HOEY ET AL. relate to an apparatus and a method for producing a virtual electrode within or upon a tissue to be treated with radio frequency alternating electric current. The apparatus includes a supply of a conductive or electrolytic fluid to be provided to the patient, an alternative current generator, and a processor for creating, maintaining and controlling the ablation process by the interstitial or surficial delivery of the fluid to a tissue and the delivery of electric power to the tissue via the virtual electrode. The method in accordance with the invention includes the steps of delivering a conductive fluid to a predetermined tissue ablation site for a predetermined time period, applying a predetermined power level of radio frequency current to the tissue, monitoring at least one of several parameters and adjusting either the applied power and/or the fluid flow in response to the measured parameters.

EDWARDS ET AL. relate to a method of treating a sphincter that provides an apparatus that includes an expandable device coupled to an introducer distal portion and an energy delivery device. The expandable device includes a first arm and a second arm, each with proximal and distal section. The expandable member has a non-deployed configuration and a deployed configuration when the first and second arm distend away from each other. The expandable device is at least partially introduced in the sphincter. At least a portion of the energy delivery device is advanced from the expandable device into an interior of the sphincter. Sufficient energy is delivered from the energy delivery device to create a desired tissue effect in the sphincter. The expandable device is then removed from the sphincter. The introducer may have one or more lumens that may be used as a path for optical fibers.

### C. Analysis

#### 1. Legal Standard

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

#### 2. Rejection over Gough et al. in view of Hoey et al.

As noted above, Gough *et al.* fail to teach distinguishing a tissue type utilizing the sensor array to measure a spectral profile of at least one portion of the tissue site. Hoey *et al.* fail to make up for this deficiency, as the document fails to make any mention of measuring a spectral profile.

#### 3. Rejection over Gough et al. in view of Edwards et al.

As noted above, Gough *et al.* fail to teach distinguishing a tissue type utilizing the sensor array to measure a spectral profile of at least one portion of the tissue site. Edwards *et al.* fail to make up for this deficiency, as there is no teaching of measuring a spectral profile.

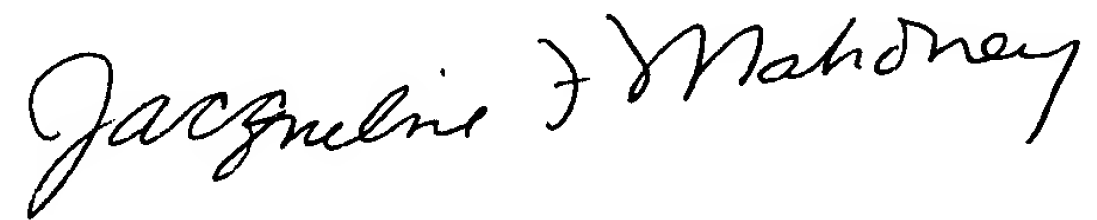
Because the references fail to teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

### **CONCLUSION**

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for Allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

A handwritten signature in black ink that reads "Jacqueline F. Mahoney". The signature is written in a cursive, flowing style.

Jacqueline F. Mahoney  
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Date: April 29, 2003

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